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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/716,417
Filing Date: November 20, 2003
Appellant(s): TANAAMI ET AL.

Ryan Chirnomas
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

Responsive to the reply brief under 37 CFR 41.41 filed on 20 November 2008, a supplemental Examiner's Answer is set forth below:

This is in response to the appeal brief filed 11 August 2006 appealing from the Office action mailed 08 August 2008 and the reply brief filed 20 November 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 4,708,931	Christian, Clifford	24 November 1987
US 2004/0087033	Schembri, Carol	06 May 2004
US 2006/0223166	Wilding et al	05 October 2006
US 2005/0202504	Anderson et al	15 September 2005
US 2004/0086872	Childers et al	06 May 2004
	Appellant's admitted prior art	
US 6,642,046	McGarry et al	04 November 2003

Christian is directed to a biochip cartridge comprising a tabular substrate comprising a detection area for evaluating a biological sample. Christian teaches that the substrate is coupled to a flexible cover that interacts with a roller-like rigid body capable of squeezing a fluid sample through gaps formed in the substrate.

Schembri is directed to a biochip cartridge comprising a tabular substrate formed from elastic material. The elastic substrate includes a detection area for detecting biopolymers.

Wilding is directed to a biochip cartridge comprising a collection area, preprocessing area and detection area connected in series using gaps as flow paths.

Biopolymers are successively transferred from the collection area to the preprocessing area and then to the detection area.

Anderson is directed to a biochip cartridge comprising a collection area, preprocessing area and detection area connected in series using gaps as flow paths. Biopolymers are successively transferred from the collection area to the preprocessing area and then to the detection area.

Appellant's admitted prior art is directed to a biochip cartridge comprising a collection area, preprocessing area and detection area connected in series using gaps as flow paths. Biopolymers are successively transferred from the collection area to the preprocessing area and then to the detection area.

McGarry is directed to a biochip cartridge comprising a microarray formed on a glass slide. The glass slide is located within the detection area of a tabular substrate.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) **Claims 2 and 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033),**

Appellant's admitted prior art, Wilding (US 20060223166), Anderson (US 20050202504) and Childers (US 20040086872).

With respect to claim 2, Christian discloses a biochip cartridge comprising a tabular substrate member (Figure 13:121). A flexible cover (Figure 13:150) is airtightly attached to the surface of the substrate member. The substrate includes an area (Figure 12:122) for detecting desired biopolymers. Christian additionally discloses additional areas (Figure 12:125 and Figure 12:124 and Figure 12:123) that are fully capable of storing biopolymers and preprocessing biopolymers. Christian additionally discloses that flow paths (Figure 12:133 and Figure 12:132 and Figure 12:131) for connecting these areas are formed in the substrate member. This is taught in column 12, line 15 to column 13, line 5. Christian, however, does not expressly disclose that the substrate is formed using an elastic material.

Schembri discloses an elastic substrate (Figure 4:334). A plurality of channels and chambers (Figure 4:340) are formed in the substrate. The substrate is capable of accommodating an area (Figure 4:332) for detecting desired biopolymers. This is disclosed in paragraphs [0087]-[0091].

At the time of the invention, it would have been obvious to create the tabular substrate disclosed by Christian from an elastic material. In paragraph [0006], Schembri indicates that flexible substrates are known in the art to be advantageous over rigid substrates in a variety of ways. Flexible substrates are more convenient and less costly to handle during manufacturing. Furthermore, elastic substrates are

beneficial because they can conform to the contour of a variety of support surfaces, and are less likely to break under impact.

The combination of Christian and Schembri still differs from the claimed invention because Christian and Schembri do not expressly indicate that biopolymers and biopolymer solutions are transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner.

Appellant discloses that it is known in the art to prepare biochip cartridges comprising a tabular substrate member attached to a flexible cover in an airtight manner. The use of fluidly connected storage (Figure 5:43), preprocessing (Figure 5:44) and detection (Figure 5:45) areas is also known. This is taught on pages 3 and 4 of the specification. Appellant further discloses on page on page 4 of the specification that it is well known in the art to use a waste liquid reservoir (Figure 5:47) for storing drainage from the detection area.

Wilding discloses a biochip cartridge comprising a collection area (Figure 16:22A), a preprocessing area (Figure 16:22B and Figure 16:16B) and a detection area (Figure 16:40) arranged in series. This is disclosed in paragraphs [0083]-[0085].

Anderson discloses a biochip cartridge comprising a collection area (Figure 3:202), a preprocessing area (Figure 3:206-214) and a detection area (Figure 3:218) arranged in series. This is disclosed in paragraphs [0167]-[0172].

Childers discloses a biochip cartridge comprising a collection area (Figure 5:118), a preprocessing area (Figure 3:120) and a detection area (Figure 3:68) arranged in series. This is disclosed in paragraph [0060].

At the time of the invention, it would have been obvious to alter the arrangement of channels and chambers in the apparatus disclosed by Christian in order to ensure that biopolymers and biopolymer solutions are transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner. As evidenced by Wilding, Anderson and Childers, this arrangement is considered to be well known in the art. This would have been beneficial because it would have guaranteed that biopolymers are adequately treated before they are moved into the hybridization area to promote more efficient detection. The admitted prior art in particular suggests that it is known to sequentially move biopolymers through storage and preprocessing areas before arrival at the detection area.

With respect to claims 4, 5, 7 and 13, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 2 wherein the biopolymers are transferred by pressing the cover with a roller-like rigid body (Figure 13:130), and squeezing each gap formed in the substrate member. This is disclosed by Christian in column 12, line 41 to column 13, line 5.

With respect to claim 6, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus in claim 2 wherein a cover is attached to both the top and bottom surfaces of the substrate member. Figure 13 of Christian

indicates that the bottom and top surfaces of the substrate are sealed by cover members 152 and 150, respectively.

With respect to claim 8, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus in claim 6 wherein the covers are formed using plastics. In column 12, lines 64 and 65, Christian indicates that the covers are made from suitable flexible materials. In column 14, lines 39-54, Christian additionally indicates that the cover members 14' and 40' of a similar biochip cartridge are made from suitable plastic materials.

With respect to claim 9, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 6 as set forth in the 35 U.S.C. 103 rejection above. Anderson additionally discloses in paragraph [0172] that it is known in the art to provide covers that are is transparent to facilitate optical detection. Appellant's admitted prior art additionally teaches that transparent cover materials are well known.

With respect to claim 10, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. In addition, Appellant's admitted prior art teaches on pages 4 and 5 that pockets (Figure 5:48, 50) for storing preprocessing solutions are formed in different positions so that when the substrate member is squeezed, a preprocessing solution is released in a time differentiated manner.

With respect to claim 11, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 2 as set forth in the 35 U.S.C. 103 rejection above. Although the above references do not disclose that the substrate is formed into a wedge shape, this embodiment of the invention would not change the function of the device in an unexpected manner. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was the recitation of relative dimensions that do not alter performance, the claimed device is not patentably distinct from the prior art. Accordingly, the claimed wedge shape is considered not to be patentably distinct from the substrate disclosed by Christian.

With respect to claim 12, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 2 as set forth in the 35 U.S.C. 103 rejection above. In addition, Appellant teaches on page 5 that the use of a valve for checking the flow of solutions is well known in the art. Appellant states that the valve opens when a solution flowing through the flow path is pressurized. Wilding, Anderson and Childers each teach that it is known in the art to provide valves within various flow paths.

2) Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033), Appellant's admitted prior art, Wilding (US 20060223166), Anderson (US 20050202504) and

Childers (US 20040086872) as applied to claims 1 and 2, and further in view of McGarry (US 6642046).

With respect to claims 19 and 20, Christian, Schembri, the admitted prior art, Wilding, Anderson and Childers disclose the apparatus set forth in claim 2 as set forth in the 35 U.S.C. 103 rejection above. Christian additionally indicates that biopolymer microarrays are mounted on a slide that is 0.127 mm wide and 0.761 mm long. Christian, however, does not expressly disclose that a carrier is a glass slide.

McGarry discloses a biochemical detection device in which biopolymer microarrays are mounted on a glass slide (Figure 2:20). The glass slide is mounted upon a substrate (Figure 1:32) in such a way that the microarrays located on the glass slide are opposite the surface (Figure 1:34) of the substrate. The glass slide and substrate form a reaction area (Figure 10:30) in which hybridization occurs. This is disclosed in column 5, line 51 to column 6, line 10. McGarry teaches in column 8, lines 23-39 that the dimensions of the glass slide are no greater than 25 mm wide by 75 mm long.

At the time of the invention, it would have been obvious to fashion the microarray carrier disclosed by Christian from a glass slide. This is due to the fact that glass is a rigid and inert substrate that is capable of covalently bonding to biochemical probes. Glass is relatively inexpensive and easily attained. The use of glass to accommodate the reactive surface of hybridization reaction chambers is well known in the art. Minimizing the size of the glass slide would also have been advantageous because it would have allowed one to reduce the volume of the hybridization detection area. This

would have reduced the amount of sample needed to conduct the experiment, and would have reduced costs associated with the purchase of reagents.

With respect to claims 21, Christian, Schembri, the admitted prior art, Wilding, Anderson, Childers and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the admitted prior art discloses that a collection area (Figure 5:43) for storing biological samples, a preprocessing solution storage area (Figure 5:44) for storing preprocessing solutions, a plurality of washing solution storage areas (Figure 5:48, 50), a combination/detection area (Figure 5:45) for performing hybridization reactions, and a waste liquid reservoir (Figure 5:47) are all provided for within the biochip cartridge. This is disclosed in column 9, line 33 to column 10, line 15. A flow path connecting all the areas and storages in series is provided.

With respect to claim 22, Christian, Schembri, the admitted prior art, Wilding, Anderson, Childers and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art discloses that the biological samples are transferred by squeezing the substrate member with a rigid roller (Figure 6:41) in the direction from the collection area toward the combination area. This is disclosed on page 5 of Appellant's specification.

With respect to claims 23 and 24, Christian, Schembri, the admitted prior art, Wilding, Anderson, Childers and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. Furthermore, McGarry teaches that the glass slide biopolymer microarray (Figure 1:20) is mounted on the substrate member

(Figure 1:32) in such a manner that the array area of the glass slide is opposed to the combination area (Figure 6:30). Additionally, a cover (Figure 1:54) formed of rigid material is attached to the substrate so that a cavity is formed therebetween.

At the time of the invention, it would have been obvious to form the hybridization/combination area disclosed by Christian from a glass slide microarray supported by a rigid cover and positioned oppositely from the substrate. This would have been beneficial because it would have created a sturdy reaction chamber within which hybridization can be monitored. The rigid cover member would have been able to provide a backing to the glass slide microarray, upon which pressure could be transmitted to force the glass slide into an airtight seal with the substrate. The subsequently formed hybridization and combination area can be constructed to be microfluidic in size, which would decrease expenses associated with the purchase of reagents.

With respect to claim 25, Christian, Schembri, the admitted prior art, Wilding, Anderson, Childers and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art teaches on pages 3 and 4 of Appellant's specification that DNA and RNA extraction mechanisms are well known, and are practiced during preprocessing operations.

(10) Response to Argument

I. Claims 2 and 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033),

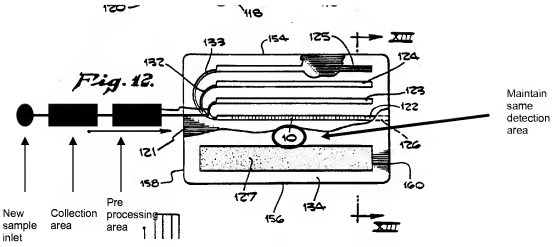
Appellant's admitted prior art, Wilding (US 20060223166), Anderson (US 20050202504) and Childers (US 20040086872).

Appellant's principle arguments are

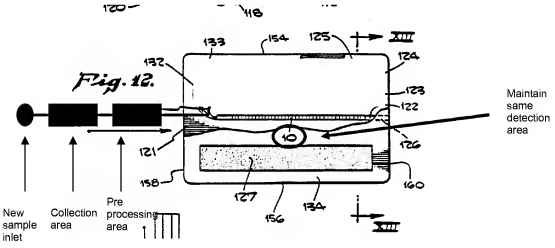
(a) It must be recognized that if a proposed combination changes the principle of operation from one type to another, prima facie obviousness has not been established. Specifically, the proposed modification changes the apparatus of Christian from a first principle of operation ("parallel" configuration) to a second principle of operation ("parallel/series" configuration).

In response to Appellant's arguments, please consider the following comments.

As a preliminary matter, it must be first noted that the proposed modification would not result in a "parallel/series" configuration as suggested by Appellant. One would have found it obvious to modify Christian according to the APA, Wilding, Anderson, and Childers to create a "series" configuration so as to sequentially transfer a sample from a collection area to a preprocessing area, and then to a detection area. Throughout prosecution, the proposition of modifying Christian to create a "series" arrangement has always been advanced – never a "parallel/series" configuration. Instead of looking to the text of the rejection, Appellant has instead fixated on the Figure illustrated in the March 7, 2007 Office Action in order to misrepresent the rejection as suggesting "parallel/series" (this continues to this day even though the drawing was removed from subsequent Office Actions when it was discovered that it did not serve to clarify as intended). The March 7, 2007 drawing reproduced below



perhaps should have been depicted as



in order to better show that the preexisting buffer chambers of Christian become obsolete and unnecessary due to the addition of upstream collection and preprocessing areas. In any event, a "series" configuration – not the "parallel/series" configuration suggested by Appellant – has always been the focus of the rejections throughout prosecution as evidenced by the text of each Office Action.

Regardless of "series" or "parallel/series," Appellant's argument pertaining to changes in a principle of operation still remains. However, for the reasons set forth in the rejections above, it would have been obvious to arrange the chambers of Christian

in series rather than parallel (or parallel/series). This conclusion is overwhelmingly supported by evidence found in the prior art. *Four* references (APA, Wilding, Anderson, Childers) have been applied to show just how uninventive and commonplace series arrangements are in the biochip art. The formation of upstream collection and preprocessing areas would have been beneficial because it would have allowed one devote an entire chamber to a specific preprocessing operation. Cell lysing operations require a chamber capable of accommodating specific chemicals or a heating element, purification operations typically require filter means, and PCR requires a heater capable of quickly cycling between multiple temperatures. It would have been advantageous to arrange each of these operations in series such that individual chambers each created for a specific process are successively arranged upstream from the detection area (detection being the ultimate goal). In the unmodified Christian reference, preprocessing is not taught because the sample is injected directly into the detection area. By arranging chambers in series prior to detection, the sample is able to move through successive chambers each specifically tailored to carry out a useful preprocessing step.

Appellant relies mainly on *In re Ratti* to show that even though all of the limitations set forth in the claims are known in the art, the proposed combination is not obvious because it would result in a change to a basic principle of construction (parallel to series). It must be considered, however, that *In re Ratti* does not stand for the proposition that any change to a principle of operation is evidence of nonobviousness. There are many examples in the case law that indicate that a change in a principle of

operation is not a bar to a finding of obviousness. For instance, the court as previously found that it is obvious to change the principle of operation from a batch process to a continuous process. *In re Dilnot*, 319 F.2d 188, 138 USPQ 248 (CCPA 1963). It also important to remember that the rejection does not rely on a *prima facie* case of obviousness – in fact, *four* reference, each supplying ample motivation, have been cited as evidence that series configuration is obvious.

The problem in *In re Ratti* was not that the Examiner suggested changing the primary reference to replicate an arrangement well known in the art (as in this case), but rather that the primary reference taught away from the proposed combination. In *In re Ratti*, the claimed invention involved a sealing means comprising a set of spring fingers. *Id.* at 810. The primary reference disclosed a similar sealing means, but without the spring fingers. *Id.* at 813. The primary reference was found incompatible with secondary references that did teach spring fingers because "the resilient element of [the primary reference] is forced so tightly into the bore and is so 'stiffened' that the use of the "resilient spring fingers of [the secondary reference] could not possibly increase the resilient deformation of [the primary reference] in the direction of the bore or increase the sealing engagement of the seal with the bore. The teaching of [the primary reference] points away from the addition of any spring element." *Id.*

The instance case is distinguishable because there is no "teaching away" problem. Rather, the shear weight of the evidence (provided in the form of *four* secondary references) suggests that the proposed redesign of Christian is not only well known in the art, but also would require only insubstantial redesign. Biochips employing

series configuration are not difficult to create, as evidenced by their clearly preferred status in the cited prior art. Unlike *In re Ratti*, there is no teaching away in Christian. Christian does not teach away from series processing since Christian is entirely silent on that topic.

(b) The proposed modification changes the apparatus of Christian from a first principle of operation (roller-based device) to a second principle of operation (pump-based device).

In response to Appellant's arguments, please consider the following comments. It is inaccurate to assert that the combination would result in a pump-based system. The primary reference already discloses a flexible cover adapted for use with a roller. The secondary references are not relied upon for teachings regarding the use of a pump, but rather only as evidence that series configurations are beneficial and well known in the art. The redesign of Christian would in no way require the use of a pump in place of a roller, or the use of a bag instead of a tabular substrate. There is simply no evidence presented that indicates that a serial channel and chamber design requires the use of a pump and bag.

(c) The Examiner has not cited any references where a solution can be sequentially transferred by a simple roller on a tabular substrate.

In response to Appellant's arguments, please consider the following comments.

In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. As previously described, Christian discloses the use of a tabular substrate in which fluid movement is induced using a roller. The APA, Wilding, Anderson and Childers each disclose the sequential transfer of solution in a biochip.

(d) The prior art must provide motivation or reason for the worker in the art, without the benefit of Appellant's specification, to make the necessary changes in the reference device.

In response to Appellant's arguments, please consider the following comments.

One of ordinary skill in the art would have found it obvious to modify Christian in order to add collection and preprocessing chambers in series prior to detection. As evidenced by the cited secondary references, the detection of nucleic acid analytes is well suited for preprocessing via a plurality of chambers in series. Generally, a cell sample is charged to a collection chamber, where it then moves to a lysis chamber for the extraction of nucleic acids. The solution is then moved to a purification chamber where cell debris is removed. The purified sample is then moved to an amplification chamber where PCR occurs (or other equivalent amplification reaction). The product is then moved to a detection chamber for analysis. The need for series construction, rather than parallel construction, is evident since the operations completed in downstream chambers are dependant on the processes carried out in previous

chambers. In this way, series configuration naturally provides for the formation of a self-sufficient lab-on-a-chip arrangement that does not rely on external laboratory equipment.

(e) The proposed modification of Christian would likely result in contamination of reagents and/or sample because sample solution would inevitably be diverted into the wash chambers.

In response to Appellant's arguments, please consider the following comments.

Again, Appellant has misinterpreted the Figure illustrated in the 07 March 2007 Office Action. Based on the discussion set forth in the first section of the "response to arguments," it should be clear that series configuration would not result in diversion into wash chambers because the position of the wash chambers of Christian would be altered in accordance with the new design. Appellant's admitted prior art, Wilding and Anderson each disclose schematics in which sample solution flows directly from a pre-processing area to a detection area without being redirected into a wash solution chamber. In light of these references, one of ordinary skill in the art would recognize how to redesign the apparatus of Christian to ensure that the sample is not needlessly moved into wash chambers.

II. Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 4708931) in view of Schembri (US 20040087033), Appellant's admitted prior art, Wilding (US 20060223166), Anderson (US 20050202504) and

Childers (US 20040086872) as applied to claims 1 and 2, and further in view of McGarry (US 6642046).

Appellant argues that this rejection is overcome based on the arguments to the rejection applied to the independent claim. All of Appellant's arguments have been fully addressed above.

(11) Response to Reply Brief

Appellant's principle arguments directed to the combination of Christian, Schembri, Appellant's admitted prior art, Wilding, Anderson and Childers are

(a) In asserting that the proposed combination would result in a series arrangement, the Examiner's Answer sets forth a new ground of rejection.

In response to Appellant's arguments, please consider the following comments.

The contention that the combination would yield a series arrangement is not new, and has been described at length in previous Office Actions. For example, the non-final rejection mailed 3/7/2007 stated on page 4 "it would have been obvious to alter the arrangement of channels and chambers in the apparatus disclosed by Christian in order to ensure that biopolymer solutions are transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner." This language strongly suggests a series configuration. Page 4 further notes that "the admitted prior art in particular suggests that it is known to sequentially move biopolymers through storage and preprocessing areas before arrival at the detection area."

These descriptions of a series combination were also repeated on page 4 of in the final rejection mailed 11/13/2007. This final rejection also noted on page 12 that "Appellant's admitted prior art, Wilding and Anderson each disclose schematics in which sample solution flows directly from a preprocessing area to a detection area without being redirected into a wash solution chamber. In light of these references, one of ordinary skill in the art would recognize how to redesign the apparatus of Christian to ensure that sample is not needlessly moved into the wash chambers." By urging that Christian would be redesigned in accordance with Appellant's admitted prior art, Wilding and Anderson (each of which strictly disclose series flow), the Office Action makes a strong statement in favor of series flow as opposed to parallel flow or series/parallel flow.

Accordingly, since the Office Actions mailed 3/7/2007 and 11/13/2007 describe the combination as exhibiting series flow, the arguments made in the Examiner's Answer do not constitute a new grounds of rejection.

Appellant additionally points to comments that were made in various Office Actions during prosecution that defended the correctness of a parallel/series combination. See pages 3-5 of Appellant's reply brief. However, these arguments by the Examiner were made strictly *in the alternative*. As noted above, the modification of Christian to series flow was described at length in the body of the rejections set forth under 35 U.S.C. 103 mailed 3/7/2007 and 11/13/2007. In responding to Appellant's arguments, it was noted that even though the prior art (Wilding, Anderson, Childers) states that a series configuration is most desired, the use of a parallel/series

configuration would also yield an operable and effective means by which to process a biological sample.

In summary, the Office Actions mailed 3/7/2007 and 11/13/2007 each proposed a combination characterized by series flow, but since Appellant misinterpreted the rejections as suggesting parallel/series, arguments in the alternative were additionally provided to indicate that even if parallel/series were being proposed, the rejections would still stand. Appellant continued to misinterpret the nature of the rejections after it was repeatedly suggested that the March 7 illustration should be ignored to the extent that it conflicts with the written text of the Office Actions.

(b) The position of the Examiner's Answer is a recycling of a ground of rejection previously withdrawn by the Examiner. The Examiner proposed a series configuration in the 8/1/2006 Office Action by combining Christian, Schembri and either Schipelsky or the APA. Examiner subsequently withdrew this rejection.

In response to Appellant's arguments, please consider the following comments.

It is agreed that this rejection was withdrawn. However, the rejection was not withdrawn due to an admission that series configuration would render the Christian device as inoperable. Instead, it was quite the opposite - that rejection was withdrawn because Schipelsky does not strongly enough disclose a series configuration (for instance, Figure 1 of Schipelsky discloses chambers 30, 32, 34, 36, 38 in parallel or parallel/series rather than series). Schipelsky was replaced by other references such as Wilding, Anderson and Childers that more clearly disclose series flow. Therefore, the

fact that the Schipelsky reference was dropped in favor of the current rejection cuts in favor of the above argument that series flow has been recited in many previous rejections, since the withdrawal of the Schipelsky rejection was motivated by a desire to more clearly demonstrate series flow as being notoriously well known in the prior art.

(c) Christian teaches away from series flow because Christian states that reagent, sample and wash solutions should not be mixed together before entering a reaction area because Christian is concerned with screening multiple analytes at a time, rather than only testing for a single antigen at a time.

In response to Appellant's arguments, please consider the following comments.

Appellant's contention that the implementation of a series configuration in Christian would render it unable to test multiple antigens is incorrect. Wilding, a biochip arranged in series, teaches in paragraph [0017] that multiple analytes are detected simultaneously by utilizing multiple binding moieties in the detection chamber. Anderson similarly teaches in paragraphs [0124]-[0125] that simultaneous detection of multiple analytes is achieved using a series flow device with a detection chamber having multiple types of probes. Accordingly, it is not accurate to state that modifying Christian to series flow would then render Christian unable to simultaneously screen multiple antigens at a time.

As noted in the rejections above, series flow provides the additional benefits of allowing one to store, process, and analyze a sample fluid all on a single chip. One of

ordinary skill in the art would have found it obvious to modify Christian to provide chambers arranged in series in order quickly and efficiently process a biological sample.

(d) The Examiner states that "it is important to remember that the rejection does not rely on a prima facie case of obviousness – in fact, four references, each supply ample motivation, have been cited as evidence that a series configuration is obvious." Prima facie obviousness is the baseline requirement for all rejections based on 35 U.S.C. 103.

In response to Appellant's arguments, please consider the following comments.

It is agreed that the above recitation is incorrectly worded. Please amend the sentence so that it reads "it is important to remember that the rejection does not rely on *the primary reference alone* – in fact, four references, each supply ample motivation, have been cited as evidence that a series configuration is obvious." This does not represent a significant change, especially when considered in the context of the surrounding words of the sentence.

(12) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Appellant may file another reply brief in compliance with 37 CFR 41.41 within two months of the date of mailing of this supplemental examiner's answer. Extensions of time under 37 CFR 1.136(a) are not applicable to this two month time period. See 37 CFR 41.43(b)-(c).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Nathan A Bowers/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Conferees:

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A Technology Center Director or designee has approved this supplemental examiner's answer by signing below:

/Gregory L Mills/

Supervisory Patent Examiner, Art Unit 1700